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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,960	03/12/2004	Paul D. Graham	58327US004	9027

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3M INNOVATIVE PROPERTIES COMPANY
PO BOX 33427
ST. PAUL, MN 55133-3427

EXAMINER

JOHNSON III, HENRY M

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/799,960

Applicant(s)

GRAHAM ET AL.

Examiner

Henry M Johnson, III

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 081604 112304.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 16 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Solis et al.; "Experimental Nonsurgical Tattoo Removal in a Guinea Pig Model with Topical Imiquimod and Tretinoin"; American Society for Dermatologic Surgery. Inc.; 28: 1 January 2002*, pgs. 83-87. Solis et al. disclose the removal of pigments using imiquimod (an immune response modifier (IRM)) and further teach this therapeutic opportunity is potentially available if pigment granules can be removed before they become permanently engulfed by the dermal macrophages.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson, "Regarding Tattoos - Is That Sunlight, or an Oncoming Train at the End of the Tunnel"; Arch Dermatology, Vol. 137, Feb. 2001; pgs. 210-212 in view of Solis et al.; "Experimental

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Nonsurgical Tattoo Removal in a Guinea Pig Model with Topical Imiquimod and Tretinoin"; American Society for Dermatologic Surgery. Inc.; 28: 1 January 2002*, pgs. 83-87. Anderson teaches tattoo removal using laser energy and that tattoos consist of phagocytosed sub-micrometer ink particles trapped in the lysosomes of phagocytic dermal cells, mostly fibroblasts, macrophages, and mast cells. When extremely intense ($100 \text{ million W/cm}^2$), brief (billionths of a second) light pulses (laser) are absorbed by these intracellular ink particles, they reach extreme temperatures. The particles fracture, undergo chemical changes, violently boil water in the cell cytoplasm, rupture the cells, and release laser-altered ink into the dermis. Some of this free ink is eliminated by lymphatic and transepidermal transport, but most of it is re-phagocytosed by somatic dermal cells within a few days. This laser may be a Q-switched Nd:YAG laser. Solis et al. disclose the removal of pigments using imiquimod (an immune response modifier) and further teach this therapeutic opportunity is potentially available if pigment granules can be removed before they become permanently engulfed by the dermal macrophages. Knowing that laser treatment yields "free" pigment granules, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the imiquimod, or other immune response modifier, as taught by Solis et al. with the laser treatment of Anderson to effect the free ink before it is re-phagocytosed.

Regarding claims 2-10, the applicant has disclosed a multitude of IRM compounds, concentrations and modes of delivery. It is further known that tattoo pigments are varied and their exact compositions rarely known, making it a non-exact procedure at best for removal of these pigments. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use any number of IRM compounds delivered by any number of modes, before during or after laser treatment because Applicant has not disclosed that any of the

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variables provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with various concentrations and/or IRM compounds because all provide the ability to eliminate or reduce tattoo pigments.

Claims 17-21 rejected under 35 U.S.C. 103(a) as being unpatentable over Solis et al. Solis et al. are discussed above. It is further known that tattoo pigments are varied and their exact compositions rarely known, making it a non-exact procedure at best for removal of these pigments. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use any number of IRM compounds delivered by any number of modes because Applicant has not disclosed that any of the variables provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with various concentrations and/or IRM compounds because all provide the ability to eliminate or reduce tattoo pigments.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M Johnson, III whose telephone number is (571) 272-4768. The examiner can normally be reached on Monday through Friday from 6:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Henry M. Johnson, III
Primary Examiner
Art Unit 3739